UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,390	09/14/2004	Willem Van Dijk	2005-1025	9012

466 7590 08/08/2007

YOUNG & THOMPSON
745 SOUTH 23RD STREET
2ND FLOOR
ARLINGTON, VA 22202

EXAMINER	
CHEN, CATHERYNE	
ART UNIT	**PAPER NUMBER**
1655	

MAIL DATE	DELIVERY MODE
08/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,390	VAN DIJK ET AL.	
	Examiner	Art Unit	
	Catheryne Chen	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-44 and 48-50* is/are pending in the application.

4a) Of the above claim(s) *31-34,38 and 40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-30, 35-37, 39, 41-44, 48-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendments filed on May 14, 2007 have been received and entered. Claims 27-44, 48-50 are pending. Claims 27-30, 35-37, 39, 41-44, 48-50 are examined on the merits. Claims 1-26, 45-47, 51 are canceled. Claims 31-34, 38, 40 are withdrawn. Applicant elected without traverse of Group I (Claims 27-30, 35-37, 41-44, 48-50) and the species plant on Jan. 18, 2007.

Response to Arguments

Applicant's arguments with respect to claims 27-30, 35-37, 39, 41-44, 48-50 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27, 35, 36, 39, 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. (Acta Botanica Sinica, 1989, vol. 31, pages 389-392).

Wang et al. teaches polysaccharides isolated from fresh leaves of Aloe vera, purified on columns of Sepharose, wherein only mannose was isolated in one fraction, the isolate improves immunity response (Abstract). The aloe was filtered in Sigma Sepharose 6B-CL (Methods).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 27-30, 35-37, 39, 42-44, 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farkas et al. (US 3360511).

Farkas teaches aloe polysaccharide containing composition for skin wound treatments as lotions, creams, ointments (column 1, lines 21-22, 30, 45-48), 35-40% glucose, 35-40% mannose, glucuronic acid (negative charged monosaccharide), molecular weight from at least 100 KD to about 620 KD (column 2, lines 1-6, 15-17, 28-30, 36-37), concentrations of the aloe polysaccharide may range from about 0.1% up to about 10% by weight (column 3, lines 31-35), product isolated by precipitation (column 3, line 54). However, it does not teach the claimed amounts for the composition.

The reference also does not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is

clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Claims 27-30, 35-37, 39, 41, 42-44, 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gayst et al. (US 4315918).

Applicant's claim is drawn to Aloe vera with D-mannose, D-glucose, monosaccharides.

Gayst et al. teaches polysaccharide gums from leguminose for medical use (column 1, lines 9-10, 19), hexose, mannose polymers, galactose residues (column 2, lines 10, 16-22), as a drinkable formulation (column 2, line 62), polysaccharides gum in 0.5:1 to 6:1 by weight ratio (column 3, lines 44-47), in acidic pH (column 6, line 38-39). However, it does not teach the claimed amounts for the composition.

The reference does not specifically teach aloe with specific amounts of mannose, glucose, and other monosaccharides. However, the extraction of aloe itself is intrinsic to contain the claimed amounts because both the reference and the claimed invention

are using the same source for extracting the claimed amounts. Thus, on the extraction of aloe the range of amounts of mannose, glucose and monosaccharide would have to be present in the extractant as claimed.

The reference also does not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

The reference also does not specifically teach formulating the composition in the forms claimed by applicant as injectable dosage. These pharmaceutical forms are well known in the art to be acceptable means of administering a pharmaceutically active substance. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that formulating the composition taught by the reference in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to formulating the composition taught by the reference in the forms

claimed by applicant. Thus, a person of ordinary skill in the art would reasonably expect that injectable dosage could be used in the composition of the reference.

Claims 27-30, 35-37, 39, 41-44, 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jia (US 2002/0071868 A1).

Applicant's claim is drawn to Aloe vera with D-mannose, D-glucose, monosaccharides.

Jia teaches topical and systemic anti-inflammatory activity of Aloe vera (paragraph 0006), pharmacologic agents of Aloe vera can be carried through epidermal barrier (paragraph 0006), complex carbohydrate preparation produced from the inner filet of the leaf of Aloe species (paragraph 0024), molecular weight of polysaccharides in range between 50-200 KD, monosaccharides contain galactose, glucose, mannose (paragraph 0026), biological vehicles may be administered orally with pharmaceutically acceptable excipients in the form of capsules, tablets, soft gel capsules (paragraph 0034). However, it does not teach the claimed amounts for the composition.

The reference does not specifically teach aloe with specific amounts of mannose, glucose, and other monosaccharides. However, the extraction of aloe itself is intrinsic to contain the claimed amounts because both the reference and the claimed invention are using the same source for extracting the claimed amounts. Thus, on the extraction of aloe the range of amounts of mannose, glucose and monosaccharide would have to be present in the extractant as claimed.

The reference also does not specifically teach formulating the composition in the forms claimed by applicant as injectable dosage. These pharmaceutical forms are well

known in the art to be acceptable means of administering a pharmaceutically active substance. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that formulating the composition taught by the reference in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to formulating the composition taught by the reference in the forms claimed by applicant. Thus, a person of ordinary skill in the art would reasonably expect that an injectable dosage could be used in the composition of the reference.

Claims 27-30, 35-37, 39, 41, 42-44, 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farkas et al. (US 3360511) as applied to claims 27-30, 35-37, 39, 42-44, 49 above, and further in view of Shupe et al. (US 6290964 B1).

Farkas teaches aloe polysaccharide containing composition for skin wound treatments as lotions, creams, ointments (column 1, lines 21-22, 30, 45-48), 35-40% glucose, 35-40% mannose, glucuronic acid (negative charged monosaccharide), molecular weight from at least 100 KD to about 620 KD (column 2, lines 1-6, 15-17, 28-30, 36-37), concentrations of the aloe polysaccharide may range from about 0.1% up to about 10% by weight (column 3, lines 31-35), product isolated by precipitation (column 3, line 54). However, it does not teach the claimed amounts for the composition and the injectable dosage.

Shupe et al. teaches anti-microbial agents from Aloe vera (column 1, line 17), as a gel or liquid to promote healing (column 4, lines 47, 60, 66), molecular weights approximately 550 KD, 470 KD, 240 KD, 160 KD, 25 KD, 4 KD have varying degrees of bactericidal or bacteriostatic activity (column 7, lines 10-13), chromatographic

separation gels (column 7, line 24), composition in a pharmaceutical acceptable aqueous medium, injectable as liquid solutions or suspensions (column 14, lines 53, 67), solid forms for solutions as capsules and the like (column 15, lines 1, 20).

The references teach uses of aloe vera extract for medicinal purposes. Thus, an artisan of ordinary skill would reasonably expect that aloe extract for medicinal purposes could be used as the types of injectable form as taught by Shupe et al. This reasonable expectation of success would motivate the artisan to use aloe extract in an injectable form in the reference composition. Thus, using aloe extract in an injectable form is considered an obvious modification of the references.

The reference also does not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Patent Examiner
Art Unit 1655

/Susan Hoffman/
Primary Examiner, Art Unit 1655
July 31, 2007